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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,940	04/13/2004	Joseph F. Bringley	87428SMR	4455

7590

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Paul A. Leipold
Patent Legal Staff
Eastman Kodak Company
343 State Street
Rochester, NY 14650-2201

EXAMINER

LE, HOA T

ART UNIT	PAPER NUMBER
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1773

DATE MAILED: 07/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/822,940

Applicant(s)

BRINGLEY, JOSEPH F.

Examiner

H. T. Le

Art Unit

1773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) 45-62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-44 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>April 2004</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-44, drawn to nanoparticles, classified in class 428, subclass 402.
 - II. Claims 45-62, drawn to method of removing metal ions, classified in class 427, subclass 212.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product can be claimed can be practiced with another materially different product such as detergent.
3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
4. During a telephone conversation with Applicant's Representative, Ms. Sarah Roberts, on June 15, 2005, a provisional election was made without traverse to prosecute the invention of group I, claims 1-44. Affirmation of this election must be made by applicant in

replying to this Office action. Claims 46-62 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Specification

5. The disclosure is objected to because of the following informalities:

Page 17, comparative example C-2 is shown in Table 2, but there's no description of C-2.

Note that there are two comparative examples C-1, one on page 16 and one on page 17.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-3, 6-10, and 15-21 are rejected under 35 U.S.C. 102(b) as being anticipated by the Ranney patent (US 6,106,866).

Claim 1: The Ranney patent teaches an in vivo agent comprising a nanoparticle base (drug carrier) and a metal ion sequestrant (metal chelator) on the surface of the nanoparticle. The nanoparticle may have a size of less than 250 nm. See Ranney, col. 15, lines 49-57 and col. 19, lines 55-57. The chelator is said to specifically chelator of iron(III) (col. 19, lines 55-56 and 61-62); therefore, its stability constant with iron (III) is necessarily greater than 10^{10} as claimed. In addition, hedroxamate, deferoxamine, and specific amine derivatives are named

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as the chelators (col. 19, lines 56-57 and col. 20, lines 13-16), and these specific chelators intrinsically possess a stability constant with iron (III) of greater than 10^{10} .

Claims 2-3: See col. 15, lines 56-57.

Claims 6-8: Hedroxamate, deferoxamine, and specific amine derivatives are named as the chelators (col. 19, lines 56-57 and col. 20, lines 13-16), and these specific chelators intrinsically possess a stability constant with iron (III) of greater than 10^{30} and thus inherently high stability constant for copper, zinc, aluminum and other heavy metals.

Claim 9: See col. 20, lines 12-13 (polyaminocarboxylate inherently contains alpha amino carboxylate functional group).

Claim 10: See col. 19, lines 55-56.

Claims 15-18: Ranney teaches nanoparticle with particle size of less than 250nm or even 25 nm (col. 15, lines 55-57). A particle size of less than 250 nm corresponds to a specific surface area of greater than 200 m²/g.

Claims 20-21: See col. 15, lines 56-57.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Ranney patent (US 6,106,866) in view of the DeVoe patent (US 4,530,963).

Claim 1: The Ranney patent teaches an in vivo agent comprising a nanoparticle of less than 250 nm as the base (drug carrier) and a metal ion sequestrant (metal chelator) on the surface of the nanoparticle as discussed above. The Ranney does not specify the materials for the nanoparticle and gives limited teaching regarding the materials suitable as the chelating agent. Similar to the Ranney patent, the DeVoe also teaches a composition comprising a carrier and a chelator on the surface of the carrier. See DeVoe, col. 2, lines 25-35. However, the DeVoe patent gives more details as to the materials for the carrier and the chelators. The DeVoe further teaches the carrier being an inorganic material (DeVoe, col. 12, lines 64-65); and specific materials as chelators that function well over a wide assortment of heavy metal ions (DeVoe, col. 2, lines 33-35 and col. 5, lines 17-21). In other words, the Ranney utilizes the new nanotechnology by employing a nanoparticle as the carrier, and the DeVoe gives specific details in selecting the components that would serve the purposes sought by Ranney (i.e. metal ion sequestration). Therefore, one having ordinary skill in the art would have found it obvious to combine the teachings of Ranney and DeVoe in order to obtain a composition comprising a nanostructured carrier and chelators that provide high stability for heavy metals, in particular iron(III). The outcome of this combination would be the best possible results in metal ion sequestration.

Claims 2-3: See Ranney, col. 15, lines 56-57.

Claims 4-5: See DeVoe, col. 12, lines 64-65 and col. 14, lines 43-44.

Claims 6-8: The hedroxamate, deferoxamine, and specific amine derivatives taught by Ranney (Ranney, col. 19, lines 56-57 and col. 20, lines 13-16) and the chelators taught by DeVoe (DeVoe, col. 2, lines 60 to col. 3, line 21) intrinsically possess a stability constant with iron (III) of greater than 10^{30} , and thus inherently high stability constant for copper, zinc, aluminum and other heavy metals.

Claim 9: See Ranney, col. 20, lines 12-13 (polyaminocarboxylate inherently contains alpha amino carboxylate functional group); and DeVoe, col. 2, lines 60-66.

Claim 10: See Ranney, col. 19, lines 55-56; and DeVoe, col. 3, lines 10-21.

Claims 11-13: See DeVoe, col. 13, line 18 to col. 14, line 39.

Claim 14: See DeVoe, col. 2, lines 60 to col. 3, line 21.

Claims 15-18: Ranney teaches nanoparticle with particle size of less than 250nm or even 25 nm (col. 15, lines 55-57). A particle size of less than 250 nm corresponds to a specific surface area of greater than 200 m²/g.

Claim 19: See DeVoe, col. 14, lines 18-24.

Claims 20-21: See Ranney, col. 15, lines 56-57.

Claims 22-44 teach the application of the composition discussed above. The Ranney patent suggests the use of the composition at col. 15, lines 7-48.

10. References not relied upon are cited as art of interest.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to H. T. Le whose telephone number is 571-272-1511. The examiner can normally be reached on 10:00 a.m. to 6:30 p.m., Mondays to Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carol Chaney can be reached on 571-272-1284. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



H. T. Le
Primary Examiner
Art Unit 1773

June 25, 2005